INSTRUMENTARIUM imaging

06 June 2000 K001928

510(K) SUMMARY

AUG 2 2000

PRODUCT, CLASSIFICATION NAME

Sigma (Digital x-ray imaging system)

System, x-ray, extraoral source, digital / MUH
Regulation number: 892.1800

MANUFACTURER:

Instrumentarium Corp. Imaging Division
P.O.Box 20 (Street Address: Nahkelantie 160)
FIN-04301 Tuusula, Finland

Phone: +358-10-394 6500
Fax: +358-10-394 6501

Contact person: Tommi Jokiniemi

UNITED STATES SALES REPRESENTATIVE (U. S. DESIGNATED AGENT):

Instrumentarium Imaging Inc.
300 West Edgerton Avenue
Milwaukee, Wisconsin 53207

Phone: 414-747-1030
Fax: 414-481-8665

INTENDED USE:

The Sigma is intended to be used for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

DESCRIPTION:

The Sigma CCD based sensor produces instant digital images. The Sigma combines radiation efficiency with excellent image quality. The Sigma allows the use of less exposure time than with conventional periapical films, thus lowering the patient dose. The sensor is connected to the CliniView software (covered by OP100 D #K992385) which gives post processing capabilities to enhance images.

Obtaining images with Sigma sensor is faster than with conventional film or phosphor plate systems, since no chemical nor any other type of processing is needed. The Sigma sensor is also more comfortable than conventional methods, since it is designed to fit well to the mouth. With the Sigma sensor any existing intraoral x-ray unit can be digitised.

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SUBSTANTIAL EQUIVALENCE:

We consider this product is similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

Sirona Sidexis	#K992644 and #K972168
Planmeca Dixi	#K000428

The analysis of technical characteristics and labeling of these devices when compared with the characteristics and labeling of Sigma supports substantial equivalence determination.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2000

Tommi Jokiniemi
Instrumentarium Corporation Imaging Division
c/o Instrumentarium Imaging Inc.
300 West Edgerton Avenue
Milwaukee, WI 53207

Re: K001928
Sigma (Digital X-ray Imaging System)
Dated: June 6, 2000
Received: June 26, 2000
Regulatory class: II
21 CFR 872.1800/Procode: 90 MUH

Dear Mr. Jokiniemi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): _____

Device Name: Sigma (Digital x-ray imaging system)

Indications for Use: The Sigma is intended to be used for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

Instrumentarium Corp. Imaging Division

Tommi Jokiniemi
Regulatory Affairs

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001928

Prescription Use ✓

(Optional Format 3-10-98)

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